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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,299	10/16/2001	Timothy R. Ryan	M190.137.101	7830

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

<b>Office Action Summary</b>	Application No. 09/982,299	Applicant(s) RYAN ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3738	

-- Th MAILING DATE of this communication app ars on th cover she t with the correspondenc addr ss --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 17-29 and 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other:  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I claims 1-16 and 30-33 in Paper No. 3 is acknowledged. The traversal is on the ground(s) that Group II, the method of repairing a heart valve, includes all of the structural limitations of the device claimed in Group I. This is not found persuasive because the method claims of Group II contain additional steps not present in the product claims which are classifiable in other classes.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 17-29 and 34-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 3.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 9-13, 15, 16, and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers US PN 5,716,397.

Myers discloses in figures 4 and 6F and line 46 of col. 2 through line 26 of col. 4 annuloplasty devices comprising a fabric sheath having position indicating markings such as colored suture and a radiopaque arcuate stiffening wire disposed within the

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sheath having a thickness less than 2.5 mm and eyelets disposed at the ends. Figure 4 shows a stiffening element generally saddle shaped in a Z-plane and arcuate in X and Y planes. Furthermore, claims 2-3 recite intended use limitations, which do not structurally limit the annuloplasty band.

5. Claims 1-4, 7, 9-13, 15, 16, and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al. US PN 5,306,296.

Wright et al. discloses in figures 2 and line 48 of col. 13 through line 66 of col. 14 annuloplasty devices comprising a fabric sheath having position indicating markings such as colored suture and a radiopaque arcuate stiffening wire disposed within the sheath having a thickness less than 2.5 mm and ends bent back on itself to form eyelets. Figure 4B shows a stiffening element generally saddle shaped in a Z-plane and arcuate in X and Y planes. Furthermore, claims 2-3 recite intended use limitations, which do not structurally limit the invention.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 5, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296 as applied to claims 1,4,7 in the 102(b) rejection above, and further in view of Carpentier et al. US PN 5,061,277.

Wright et al. discloses an annuloplasty device meeting the structural limitations of claims 5, 6, and 8 as described above, but lacks the express disclosure of the stiffening element having the three particular radii of curvature and a silicon overmold. Carpentier et al. teaches in figures 1 and 3, lines 9-16 of col. 3, and line 57 of col. 3 through line 7 of col. 4 an annuloplasty device having a sheath and stiffening ring wherein the stiffening ring has the three particular radii of curvature (of claim 8) to properly fit the shape of the natural mitral valve, and furthermore adds a silicone overmold to make the band soft and compressible as well as more resilient.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty sheath and stiffening element disclosed by Wright et al. by using the particular shape and overmold taught by Carpentier et al. in order to properly fit the shape of the natural mitral valve and make the band soft and compressible as well as more resilient.

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296 or Myers US PN 5,716,397 as applied to claim 1 in the 102(b) rejections above, and further in view of Loch et al. US PN 6,174,332.

Wright et al. or Myers discloses an annuloplasty device meeting the structural limitations of claim 14 as described above, but lacks the express disclosure of the

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sheath being formed of biological tissue. Loch et al. teaches in lines 44-57 of col. 3 an annuloplasty ring having a sheath made of biological tissue to provide sufficient biocompatibility.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty sheath disclosed by Wright et al. or Myers by using biological tissue as taught by Loch et al. in order to provide sufficient biocompatibility.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WHM

WHM

April 2, 2003

  
CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700